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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,723	01/17/2001	Yasuo Koishihara	53466/295	4861

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/760,723	KOISHIHARA, YASUO	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-24* is/are pending in the application.

4a) Of the above claim(s) *14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13 and 15-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claim 14 stands withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

Claims 13 and 15-24 are being acted upon.

2. Applicant's amendment and remarks, filed 12/06/05, are acknowledged. In view of said amendment and remarks the previous rejections under 35 U.S.C. 112, first paragraph for the introduction of new matter into the claims, as well as the rejections for lack of enablement regarding sufficient showing that anti-HM1.24 antibody actually binds the amino acid sequence of SEQ ID NO:1 and sufficient evidence that the claimed method could inhibit lymphocyte activation without killing the lymphocytes, have been withdrawn. Additionally, the previous rejection under the second paragraph of 35 U.S.C. 112 has also been withdrawn.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 23 and 24 stand, and newly amended Claims 13 and 15-22 are, rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,298,420 (1994) in view of Goto, T., et al. (1994, IDS) for the reasons of record set forth in the paper mailed 9/22/03.

As set forth previously, The '420 patent teaches a method of inhibiting B lymphocyte activation (by killing the lymphocyte) for the treatment of an autoimmune disease or a B cell cancer comprising administering a monoclonal antibody which binds B cells (see particularly column 1, lines 27-39 and column 6, lines 45-57).

The reference teaching differs from the claimed invention only in that it does not teach the use of the chimeric, humanized monoclonal antibody HM1.24 which binds SEQ ID NO:1.

Goto, T., et al. teaches the use of the chimeric, humanized monoclonal antibody HM1.24 which binds SEQ ID NO:1 on terminally differentiated B cells for the treatment

of multiple myeloma (see particularly page 1922, column 2, paragraph 1 and page 1929, column 1 paragraph 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method of inhibiting B lymphocyte activation (by killing the lymphocyte) for the treatment of an autoimmune disease, comprising administering a monoclonal antibody, as taught by the '343 patent, employing the humanized monoclonal antibody HM1.24 which binds SEQ ID NO:1, as taught by Goto, T., et al. as the specific monoclonal antibody. One of ordinary skill in the art at the time the invention was made would have been motivated to use the HM1.24 because said antibody was known to selectively bind terminally differentiated B cells, as taught by Goto, T., et al., and would thus, be an obvious choice for the elimination of said cells and the treatment of any disease (such as a B cell-mediated autoimmune disease) which said cells mediate. Note that the substitution of equivalents, in this instance different B cell-binding antibodies, is considered to be obvious.

Applicant's arguments, filed 12/06/05, have been fully considered but they are not persuasive. Applicant reviews the references and argues that, "The combination of the '420 patent and the Goto et al. reference fails to teach or suggest the claimed invention. The teachings of the '420 patent do not extend beyond migis antigens, and Goto et al. did not identify HM1.24 as being a migis antigen."

Applicant's conclusions regarding the teachings of the '420 patent may be correct as for as they go, however, the reference also teaches that the desirability of the immunosuppression of *all* five isotypes of B cells (see particularly, column 3, lines 10-30), a type of immunosuppression (through elimination or control of immune cytolytic or regulatory mechanisms) for which the HM1.24 antibody would be suitable. Thus, the use of the antibody of Goto et al. in the method of the '420 patent remains obvious.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 13 and 15-22 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the specification provides insufficient evidence

that the antibody employed in the claims could bind T lymphocytes as is required by the claimed method,

As set forth previously, a further review of Goto et al. shows that the reference teaches that the anti-HM1.24 antibody is B cell specific. Table 1 teaches that the antibody does not bind T cells. Thus, the teachings of Goto et al. directly contradict the findings of the instant disclosure. The most scientifically reasonable conclusion would be that the antibody binds some T cells (i.e., the T cells of the specification), but not others (i.e., the T cells of Goto et al.). Clearly then, an unpredictability has been established, at least as the claimed invention encompasses a method that requires the binding of the amino acid sequence of SEQ ID NO:1 and the binding of T cells.

Applicant's arguments, filed 12/06/05 have been fully considered but they are not persuasive. Applicant argues, "... there is ample evidence that the antibodies employed in the claims can bind T lymphocytes ... As can be seen from Fig. 2, although HM1.24 antibody does not bind to T lymphocytes without blast formation".

Even ignoring the teachings of Goto et al., it is noted that the claims encompassing a method wherein T lymphocytes are inhibited are not limited to the inhibition of PHA-stimulated T cell blasts. Accordingly, the method as broadly claimed is not reasonably enabled for the scope of the claims.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571)272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's

voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

10. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/7/06

G.R. Ewoldt, Ph.D.
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Technology Center 1600